Total hip arthroplasty: Anterior supine intermuscular versus transgluteal approach, a prospective study.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26281

Bron
NTR

Verkorte titel
ASI study

Aandoening

total hip arthroplasty, anterior supine intermuscular

Ondersteuning

Primaire sponsor: Spaarneziekenhuis Hoofddorp en tevens het Stimulerinsfonds van het Linneusinstituut
Overige ondersteuning: Stimuleringsfonds van het Linneusinstituut

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Function: Harris Hip Score.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

We present the design of a open randomised controlled study of anterior supine intermuscular (ASI) versus transgluteal approach of total hip arthroplasty (THA). The study is designed to evaluate functional outcome after both approaches.

Methods/Design:

in this randomized controlled trial, 120 consecutive primary noncemented THAs in 120 patients were assigned to one of two groups (ASI or transgluteal). The primary outcome was functional outcome (Harris hip score) at six weeks and one year postoperatively.

Conclusion:

By making this design study we wish to contribute to more profound research on the anterior approach of total hip arthroplasty.

Doel van het onderzoek

The hypothesis of this study is patients with a primary total hip arthroplasties through the anterior supine intermuscular approach will show faster improvement in in walking ablility and mobilization in the postoperative period in comparison with those managed with the transgluteal approach.

Onderzoeksopzet

2 days, 6 weeks, 3 months, 6 months, 1 year.

Onderzoeksproduct en/of interventie

Total hip arthroplasty through anterior supine intermuscular and transgluteal approach.

Anterior supine intermuscular approach:

Supine position of the patient on the operating table with the possibility of hyperextension in the mid-table in order to facilitate femoral exposure. Anterior incision, 6-9 cm long, starting approximately 2cm lateral and 5 cm distal of the anterior iliac spine. Incision of the fascia, blunt preparation in the intermuscular space between tensor fascia latae muscle and sartorius muscle. Exision of the anterior parts of the capsule. Osteotomy of the femur by hyperextension, adduction and externeal rotation of the leg, incision of the posterior capsule for easy anteriorrization of the femur. Reaming and implantation of the acetabular component. next , the femur was externally rotated and the capsule carefully detached from the greater trochanter. the entrance into the meddulary canal was lifted to achieve unimpaired access for the offset of broaches. a special two-prolonged retractor was inserted between the tendons of the gluteus medius and minimus and the greater trochanter to provide additional leverage. the adducted femur was broached for a cementless stem. since no muscles were split, the fascia between the
Sartorius muscle and tensor muscle was sutered. The subcutaneous fat and skin were sutured.

Surgical technique transgluteal approach:

Supine position of the patient on the operating table. A straight lateral incision is made over the greater trochanter. The iliotibial tract is exposed and divided longitudinally just posterior to the insertion of the tensor fascia lata. The ventral third of vastus lateralis muscle and the gluteal muscle was detached from the bone in one coherent layer using diathermy. The exposed capsule was then opened, and the femoral head was dislocated. Following osteotomy of the femoral neck, the cup was reamed for a cementless cup. For the preparation of the femoral canal, the operated limb was adducted below the contralateral one and rotated outward. The external rotators near the intertrochanteric fossa were tenotomised. While holding back the gluteal muscles, the femur was broached for an uncemented stem. After implantation, the gluteus medius and vastus lateralis was adapted. Then, de fascia latea was closed. The subcutaneous fat and skin were sutured.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Indication THA;

2. Primairy arthrosis;

3. BMI<30 kg/m;

4. General anesthesia;

5. <80 jaar;

6. ASA-classification I en II.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous surgery of the hip before;

2. Fractures;

3. Inflammatory polyarthritis;

4. Local anesthesia;

5. CVA/TIA or MI last half year;

6. ≥ 80 year;

7. ASA-classification III and IV.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3373
NTR-old	NTR3520
Ander register	METC / CCMO : M010-072 / NL3394609410;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A